

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
(Attorney Docket No. 98-736-A)

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In re the Application of:

Hall et al.

Application No.: 09/441,966

Filing Date: November 17, 1999

For: A Method For Accelerating the  
Rate of Mucociliary Clearance

Examiner: Steadman, David J.

Art Unit: 1652

Confirmation No.: 5234

**PETITION FROM FINAL RESTRICTION REQUIREMENT**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

The applicants hereby petition the Commissioner to review the requirement for restriction that was made final in the office action mailed July 2, 2002. This petition is filed pursuant to 37 C.F.R. § 1.144.

The Patent Office issued a supplemental restriction requirement in an office action mailed April 2, 2002, in which restriction of the application to one of sixteen inventions was required. The Patent Office asserted that restriction was proper because "the inventions listed as Groups I-XVI require divergent sequence searches, thus establishing the serious burden of search on the examiner." In a response mailed April 15, 2002, the applicants elected Group XVI, corresponding to claims 1-10 and 15-18 and SEQ ID NO:8, with traverse. By traversing the restriction requirement the applicants preserved their right of petition. Therefore, this petition is proper under MPEP § 818.03(c).

§ 803 of the MPEP discusses the circumstances in which restriction of an application is appropriate. For example, it clearly states, “If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits.” § 803 continues: “For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02.” In turn, § 808.02 describes “separate status in the art” as follows: “Even though they are classified together, each subject can be shown to have formed a separate subject for inventive effort when an explanation indicates a recognition of separate inventive effort by inventors. Separate status in the art may be shown by citing patents which are evidence of such separate status, and also of a separate field of search.” § 808.02 also defines “different field of search”: “Where it is necessary to search for one of the distinct subjects in places where no pertinent art to the other subject exists, a different field of search is shown, even though the two are classified together.”

In this case, Groups I-XVI all reside within the same classification (class 514, subclass 2). Moreover, the Patent Office has not alleged that Groups I-XVI have achieved a status in the art separate from each other. Rather, the Patent Office simply stated that a serious burden exists because “Groups I-XVI require divergent sequence searches.” However, even if this were true, it does not meet the definition of “different field of search” under MPEP § 808.2, since the Patent Office has not shown that “it is necessary to search for one of the distinct subjects in places where no pertinent art to the other subject exists.” Accordingly, the applicants respectfully submit that the Patent Office has failed to establish a *prima facie* case that there is a serious burden on the examiner to examine the application in its entirety.

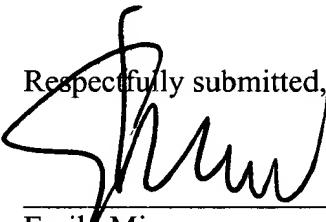
In addition, contrary to the Patent Office's statement that "the inventions listed as Groups I-XVI require divergent sequence searches," the inventions could be completely searched in a prior art search for just one or two amino acid sequences. As shown in the attached amino acid sequence alignment (see Exhibit A), the fifteen amino acid sequences recited in the pending claims share a common structure (note that the claims were amended by deleting aprotinin). For example, all fifteen sequences have a region of at least 50 amino acids that is identical to a portion of SEQ ID NO:52. Therefore, a search of the prior art for SEQ ID NO:52 would likely reveal all prior art potentially relevant to all fifteen sequences. Moreover, thirteen of the fifteen sequences contain the complete amino acid sequence of either SEQ ID NO:3 or 5. Therefore, a search of the prior art for SEQ ID NO:3 and 5 would likewise reveal all prior art potentially relevant to all fifteen sequences recited in the claims. Coupled with the fact that Groups I-XVI all reside within the same classification (class 514, subclass 2) and that the Patent Office has shown neither that the Groups have a separate status in the art nor that searches in different fields are required, the common structure of all amino acid sequences ensures that examination of the entire application can be made without serious burden. Accordingly, the applicants respectfully request withdrawal of the restriction requirement.

In the event that the Patent Office decides not to withdraw the restriction requirement, the applicants respectfully request that the Patent Office reduce the number of groups to which restriction is required. For example, the Patent Office could require restriction to one of two groups, SEQ ID NO:6 and 7 or SEQ ID NO:52, 1, 2, 45, 49, 47, 71, 70, 3, 50, 8, 4, and 5, since SEQ ID NO:7 is entirely contained within SEQ ID NO:6 and SEQ ID NO:5 is entirely contained within each of SEQ ID NO:52, 1, 2, 45, 49, 47, 71, 70, 3, 50, 8, and 4. Alternatively, the Patent Office could require restriction to one of three groups, SEQ ID NO:4, 5, and 8, SEQ ID NO:6

and 7, or SEQ ID NO:52, 1, 2, 45, 49, 47, 71, 70, 3, and 50, since sequences in the first group contain only the first Kunitz domain of Bikunin, those in the second group contain only the second Kunitz domain, and those in the third group contain both Kunitz domains.

To summarize, the applicants respectfully submit that the Patent Office has not established a *prima facie* case that a serious burden to search the entire application exists and that, in fact, a serious burden does not exist due to the common structure of the amino acid sequences recited in the amended claims. Therefore, the applicants respectfully request withdrawal of the restriction requirement. In the alternative, the applicants respectfully request that the Patent Office reduce the number of groups to which the application is restricted.

Dated: October 2, 2002

Respectfully submitted,  
  
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## Exhibit A

1

SEQIDNO52	ADR ERSIDFCLV SKVUGRCRAS MPRWVYNTVD GSCQLFYVGG CDGNSNNYLT KEECULKKCAT VTNATGDLA
SEQIDNO1	A GSFLAWLGSL LLSGVLA.....
SEQIDNO2	MLRAEA DGVSRLIGSL LLSGVLA.....
SEQIDNO45	MAQLCGLRRS RAFLALIGSL LLSGVLA.....
SEQIDNO9	MAQLCGLRRS RAFLALIGSL LLSGVLA.....
SEQIDNO47	MAQLCGLRRS RAFLALIGSL LLSGVLA.....
SEQIDNO71	.....
SEQIDNO70	.....
SEQIDNO3	.....
SEQIDNO50	.....
SEQIDNO8	.....
SEQIDNO4	.....
SEQIDNO5	.....
SEQIDNO6	.....
SEQIDNO7	.....

100

SEQIDNO52	TSRNAAADSSV PSAPPRDOS EHSDDMMFNYE EYCTANAVTG PCRASFPRWY FDVERNSCNN FIYGGCRGNK NSYRSBEBACM LRCFPRQENP PIPLGSK
SEQIDNO1	.....
SEQIDNO2	.....
SEQIDNO45	.....
SEQIDNO49	.....
SEQIDNO47	.....
SEQIDNO71	.....
SEQIDNO70	.....
SEQIDNO3	.....
SEQIDNO50	.....
SEQIDNO8	.....
SEQIDNO4	.....
SEQIDNO5	.....
SEQIDNO6	.....
SEQIDNO7	.....

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252

SEQIDNO52	LAGAVS
SEQIDNO1	LAGAVS
SEQIDNO2	LAGAVS
SEQIDNO45	LFLGASMVLI LFLGASMVLY IRVARRNQER ALRTWSSGD DKEQLVKNTY VL
SEQIDNO49	LFLGASMVLI LFLGASMVLY IRVARRNQER ALRTWSSGD DKEQLVKNTY VL
SEQIDNO47	LFLGASMVLI LFLGASMVLY IRVARRNQER ALRTWSSGD DKEQLVKNTY VL
SEQIDNO71	LFLGASMVLI LFLGASMVLY IRVARRNQER ALRTWSSGD DKEQLVKNTY VL
SEQIDNO70	LFLGASMVLI LFLGASMVLY IRVARRNQER ALRTWSSGD DKEQLVKNTY VL
SEQIDNO3	.....
SEQIDNO50	.....
SEQIDNO8	.....
SEQIDNO4	.....
SEQIDNO5	.....
SEQIDNO6	.....
SEQIDNO7	.....